



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: AAV

Mediated Aquaporin-1 Gene Transfer to Treat Sjögren's Syndrome

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Milo, LLC, a company having its headquarters in Cleveland, Ohio, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/695,753, filed 20 April 2011 (HHS Ref. No. E-139-2011/1-US-01]), and PCT Patent Application No. PCT/US13/57632, filed 30 August 2013 (HHS Ref. No. E-139-2011/1-PCT-02), entitled "AAV Mediated Aquaporin-1 Gene Transfer to Treat Sjögren's Syndrome." The patent rights in these inventions have been assigned to or exclusively licensed to the Government of the United States of America. The territory of the prospective license may be worldwide and the field of use may be limited to: "the use of the Licensed Patent Rights, limited to AAV mediated aquaporin-1, for the treatment of Sjögren's syndrome in humans."

Upon the expiration or termination of the Start-Up Exclusive Evaluation Option License Agreement, Milo will have the exclusive right to execute a Start-up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License

Agreement, with no greater field of use and territory than granted in the Start-Up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Vince Contreras, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4711; Facsimile: (301) 402-0220; E-mail: vince.contreras@nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The subject technology includes methods of treating Sjögren's syndrome by using recombinant adeno associated virus (rAAV) serotypes as vectors to deliver a gene that expresses AQP1. Aquaporin-1 is a pore protein that selectively channels water molecules across the cell membrane. Using animal models that mimic the dry mouth symptoms (xerostomia) of Sjögren's, it was discovered that there was restoration of fluid movement upon expression of AQP1. This potentially represents a long-term treatment for restoring exocrine gland function in Sjögren's patients where salivary gland activity is significantly reduced.

The prospective Start-Up Exclusive Evaluation Option License Agreement will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent

Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives, within fifteen (15) days from the date of this published notice, written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

Complete applications for a license in the prospective field of use that are filed in response to this Notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. Comments and objections submitted in response to this Notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 7, 2014.

Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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